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August 12, 2019

VIA ECF

The Honorable Joel Schneider
United States Magistrate Judge
District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets
Camden, NJ 08101

Re: In re Valsartan NDMA Products Liability Litigation
Case No. 1:19-md-02875-RBK-JS

Dear Judge Schneider:

This letter responds to plaintiffs' letter to the Court dated August 6, 2019 (Dkt. 178), asserting purported "global" deficiencies in the core discovery produced pursuant to the Court's April 29, 2019 Order (Dkt. 88) ("Core Discovery Order"), and raising specific deficiencies in the core discovery productions of certain defendants.

Defendants have produced core discovery ***to the letter*** of the Core Discovery Order. This production of core discovery has and will serve the purpose of allowing this matter to proceed expeditiously. The court's objective of ensuring that plaintiffs have key information that goes to the "crux" of their claims in order to enhance the efficiency of forthcoming general discovery has been fulfilled.

The claimed global deficiencies are not deficiencies at all. Instead, plaintiffs are using that term to lodge new requests for information that surpass the requirements of the Core Discovery Order, and to request that defendants provide plaintiffs with lists of information that will save them from having to review the core discovery that has been produced. These new requests exploit the Core Discovery Order to obtain information that may or may not be the subject of general discovery under Rule 26.

However, the Court has demarked the line between core discovery and Rule 26 discovery. Core discovery is circumscribed to information that is "(1) easily identifiable, (2) unquestionably relevant and not privileged, (3) relatively simple to retrieve, and (4) discrete." *See* Core Discovery Order at n.1. Core discovery is intended to narrow the focus of Rule 26 discovery. *See* Tr. of Apr. 10, 2019 Conference (Dkt. 101) at 31:14-17 ("But we think it's important that you get these core documents. It'll . . . guide your discovery in this case so you don't do down a rabbit hole."). Indeed, in tailoring the Core Discovery Order, the Court rejected requests for information tantamount to general discovery. *See* Dkt. 101 at 28:20-22 ("I think the plaintiffs, rather than focusing on what I envision as 'core documents,' served the Rule 34 document request. That was not the purpose of this effort.").

Plaintiffs' proposed morphing of core discovery into general discovery is especially inappropriate given that the merits and scope of plaintiffs' claims have not been reviewed by the Court, and because, to date, core discovery has been entirely one-sided. Defendants have produced approximately 20,000 documents, totaling over 200,000 pages, while plaintiffs have produced ***nothing***. Plaintiffs' Fact Sheets, the analogue to defendants' core discovery, are still being drafted, and the production of any information by plaintiffs potentially substantiating their claims seems to be months away.

To be sure, the material the core discovery defendants have produced fulfills the objective of the Core Discovery Order. As the Court has explained, "the crux of the entire lawsuit" is plaintiffs' claim that valsartan API was manufactured with a contaminant. *See* Tr. of July 24 Status Conference with Judge Kugler (Dkt. 176) at 6:2-4 ("In any claim that you have, they're going to find out or at least ask about what did you know, how did you know it, and when did you know it. I mean, that's the crux of the entire lawsuit."). The core discovery that defendants have produced—Drug Master Files ("DMFs"), Abbreviated New Drug Applications ("ANDAs"), communications with the FDA about the alleged contamination, and Form 483s, Establishment Inspection Reports, CGMP inspection reports, and warning letters pertaining to the facilities where valsartan API was manufactured, and lists of U.S. customers—are directly relevant to the "crux" of this action.

For these reasons, and the specific reasons set forth below, the Court should deny plaintiffs' new requests and resist any expansion of the Core Discovery Order.

I. Plaintiffs' New Global Requests Should be Denied

In communications with counsel and their letter to the Court, plaintiffs have made wide-ranging requests for new information not required by the Core Discovery Order, couching these new requests as alleged deficiencies in the core discovery productions. These requests include:

- "a comprehensive list of all ANDA applications submitted to the FDA by each Defendant which references or incorporated the Valsartan API," including "any correspondence with the FDA regarding those ANDA applications;"

- "a comprehensive list of all manufacturing facilities which are involved in the manufacturing of the adulterated Valsartan products, including finished dose manufacturing, and testing facilities;"

- "a comprehensive list of all testing conducted on the Valsartan products, and the corresponding bates ranges for those results provided in Defendants' productions;"

- "a list of every test and test result from each testing facility, for each defendant's (or an affiliate or independent entity's) testing of valsartan;" and

- "the corporate organization/hierarchy of each defendant."

See Letter dated July 31, 2019, attached as Exhibit A, Letter dated August 6, 2019 (Dkt. 178), and email dated August 7, 2019, attached as Exhibit B. In addition, plaintiffs request defendants re-produce the ANDA files in eCTD format.

A. FDA Communications Concerning ANDA Applications

The Core Discovery Order calls for the production of the "Valsartan ANDA file" and "ANDA file for each involved finished dose formulation." Dkt. 88 at ¶¶ 6(a)(1) and 6(b)(1). Defendants have produced this information.

Contrary to plaintiffs' suggestion, while the Court ordered the production of FDA correspondence concerning a number of topics, *see* Dkt. 88 at ¶ 6(a)(3), it ***did not*** order production of correspondence regarding ANDA applications. Indeed, unlike the ANDA's themselves, which have been produced, and which bear directly on the manufacture of valsartan, ***correspondence*** about the ANDAs may or may not have any bearing on the facts at issue here, let alone the "crux" of this case. Thus, even if relevant, which has not been established, such communications are the kind of general, non-specific information for which Rule 34 document requests are intended—they are not the kind of information the Core Discovery Order was meant to cover.

B. Materials Relating to Finished Dose Manufacturing Facilities

As Judge Kugler acknowledged, "the crux of the entire lawsuit" is the allegation that the valsartan API was manufactured with a contaminant. *See* Dkt. 176 at 6:2-5. Thus, the Core Discovery Order requires defendants to produce "all FDA Form 483's, Establishment Inspection Reports, CGMP inspection reports, and warning letters, as well as the responding defendants' responses to same, regarding any facility ***that manufactured or supplied the API at issue***." *See* Dkt. 88 at ¶ 6(a)(3) (emphasis added). Defendants satisfied this obligation.

Plaintiffs now claim the Core Discovery Order should be read to include finished dose manufacturing facilities in addition to API manufacturing facilities. While information about the

finished doses of the recalled valsartan may have some as yet defined bearing on the claims or defenses in this action, "Form 483's, Establishment Inspection Reports, CGMP inspection reports, and warning letters, as well as the responding defendants' responses to same" pertaining to finished dose facilities are not so "unquestionably relevant" to the manufacture of the API that such information should be considered core discovery. To the contrary, production of this information would eviscerate the distinction between core discovery and general Rule 26 discovery, rendering the circumscription of the Core Discovery Order meaningless.

C. Lists of Information and Bates Ranges

Plaintiffs request that defendants generate several lists that would allow them to avoid reviewing the core discovery in detail, including lists of (1) "***all*** ANDA applications to the FDA by each Defendant which referenced or incorporated the adulterated [v]alsartan API," (2) "***all*** manufacturing facilities… including finished dose manufacturing, and testing facilities," and (3) "***every*** test and test result from each testing facility, for each defendant's (or an affiliate or independent entity's) testing of valsartan." *See* Exhibit A at 3-4; Exhibit B. Plaintiffs also request that defendants identify the testing results already produced by Bates range.

These requests should be denied for several reasons.

- The core discovery already contains the information plaintiffs now ask defendants to compile in lists. For example, the DMFs, ANDAs, and FDA correspondence defendants have already produced contain information from which plaintiffs can readily identify defendants' various valsartan API manufacturing, finished dose manufacturing, and testing facilities.[1]

- The Core Discovery Order required the production of documents that are "easily identifiable" and "relatively simple to retrieve," and did not require defendants to generate information not kept in the ordinary course of business so that plaintiffs do not have to review the core discovery. The burden on defendants of having to create such lists is obvious. For example, each of the core discovery defendants manufactures other sartans, and it is unknown whether the ANDAs for those drugs "reference" valsartan API. It would be unduly burdensome to require defendants to review those ANDAs to make such determination in order to generate a list for plaintiffs' litigation purposes.

[1] Examples of such facility information include PRINSTON00000001 (identifying the facilities where ZHP manufactures valsartan API and finished dose products); PRINSTON00000590–591 (identifying testing facility for ZHP's valsartan products); PRINSTON00000802–803 (same); and PRINSTON00001093–1094 (same).

- Plaintiffs' new request for "a list of ***every test and test result from each testing facility***, for each defendant's (or an affiliate or independent entity's) testing of valsartan" goes well beyond the scope of core discovery. It may never be necessary to require each defendant to produce evidence of ***every*** test ever conducted on valsartan, and such a requirement would be unquestionably overly burdensome as core discovery. For example, to the extent it is not contained in the extensive documents already produced, any additional testing information concerning ZHP's valsartan products is likely located in its Chinese offices. Testing information, especially as it relates to the recalled valsartan, is contained in the documents defendants have already produced or will produce as further testing is provided in future correspondence with the FDA.[2]

D. eCTD Format

Defendants have produced the ANDA files in the form called for in the ESI Protocol, which plaintiffs insisted on. *See* June 11, 2019 Letter from A. Slater (Dkt. 116) at 2 (requesting that core discovery be produced "in compliance with the ESI [P]rotocol"). Plaintiffs now want defendants to re-produce their ANDA files in eCTD format, a format that falls outside the ESI Protocol. eCTD (electronic common technical document) is a format by which certain information is submitted to the FDA.

The very reason that defendants agreed to produce the ANDA files with extensive metadata, as required by the ESI Protocol, was to allow plaintiffs to easily review the production. Supplementing the ANDA production with files in eCTD format would place a substantial burden on defendants, requiring hundreds of attorney hours to review and redact documents for confidential or privileged information. Requiring defendants to re-produce the ANDA in a manner more burdensome than that required by the agreed ESI Protocol contradicts both the ESI Protocol and the Core Discovery Order.

E. Corporate Organizational Information

Plaintiffs also request the corporate/organizational hierarchy of each defendant. While such information may well be discoverable, it falls outside the Core Discovery Order and fails to address the core issues of this litigation: when, why and how valsartan API was manufactured with a contaminant. Though plaintiffs may be entitled to this information as general discovery, its disclosure is not necessary at this time.

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[2] Examples of such testing results include PRINSTON00000019–46, PRINSTON00000066–69, PRINSTON00000191–226, and PRINSTON00000264–268.

II. Defendant-Specific Issues

Each individual defendant is meeting and conferring with plaintiffs on the issues specific to its core discovery production. While defendants believe that many of the remaining issues can be resolved prior to the August 14 Status Conference, each individual defendant will be prepared to discuss any outstanding issues at the Conference, and each has provided the information below regarding their respective discussions with plaintiffs.

A. The Prinston Defendants

By letter dated July 31 (Exhibit A), plaintiffs identified three purported deficiencies with the Prinston Defendants' productions: (1) a purported failure to identify categories of documents by Bates range; (2) a purported failure to produce certain EIRs and Form 483s responsive to the Core Discovery Order; and (3) a purported failure to produce all supplements to the manufacturing process from 2010 to present. On August 5, Prinston responded by email, addressing each of those issues to plaintiffs' satisfaction. Specifically, Prinston identified various categories of documents by Bates number, agreed to search for and produce additional documents, and confirmed that it had produced all supplements to the manufacturing process. In their August 6 submission to the Court, plaintiffs indicated that they would inform the Court of any specific unresolved issues relating to the Prinston Defendants' productions. No such issues have been raised by plaintiffs.

B. Aurobindo Pharma USA, Inc. and Aurolife Pharma LLC

By letter dated July 31, plaintiffs identified several purported deficiencies with the production by Defendants Aurobindo Pharma USA, Inc. and Aurolife Pharma LLC. On August 6, counsel for Aurobindo Pharma USA, Inc. and Aurolife Pharma LLC responded by letter, addressing the issues plaintiffs raised. Specifically, counsel for Aurobindo Pharma USA, Inc. and Aurolife Pharma LLC identified various categories of documents by Bates number and agreed to search for and produce additional documents. In their August 6 submission to the Court, plaintiffs indicated that other than the purported global issues and whether Aurobindo Pharma USA, Inc. and/or Aurolife Pharma LLC have possession, custody or control over API information, the parties believe they will be able to resolve the remaining issues.

Aurobindo Pharma USA, Inc. and Aurolife Pharma LLC have produced all core discovery that is in their possession, custody and control in accordance with the Core Discovery Order. Plaintiffs' July 31 letter asked what steps, if any, have been taken to obtain responsive documents from foreign Co-defendant, Aurobindo Pharma Ltd. Counsel for Aurobindo Pharma USA, Inc. and Aurolife Pharma LLC responded that plaintiffs' request falls outside the scope of the Core Discovery Order, which required responding defendants to identify where core discovery is located "[t]o the extent [they] contend[] [they] do not have possession, custody or control of any of the listed documents." Accordingly, in their cover letter enclosing their production, Aurobindo

Pharma USA, Inc. and Aurolife Pharma LLC stated that API information is located at Aurobindo Pharma Ltd. in India. Further, they noted their observation that Aurobindo Pharma Ltd. has not been served. Counsel for Aurobindo Pharma USA, Inc. and Aurolife Pharma LLC is unaware of the current status of service on Aurobindo Pharma Ltd. but notes that no return of service has been filed.

C. The Torrent Defendants

As an initial mater, contrary to plaintiffs' suggestion, Torrent has not "taken the position that documents located at related entities need not even be attempted to be obtained and produced[.]" Torrent is not withholding any document on this basis.[3]

Torrent will address each of the specific issues plaintiffs raised regarding Torrent's compliance with the Core Discovery Order in turn:

1. **Torrent has complied with ¶ 5 of the Core Discovery Order**. Paragraph 5 of the Core Discovery Order requires that "responding defendants shall identify the Bates numbers of the documents responsive to each category of documents listed in paragraph 6[.]" Dkt. 88 at ¶ 5. On July 19, 2019, Torrent provided a letter that complied with this directive, and provided the beginning bates and ending bates for each category of documents in ¶ 6 of the Core Discovery Order:

Category	Beg Bates	End Bates
ANDA 202377	TORRENT-MDL2875-00000001	TORRENT-MDL2875-00001303
ANDA 201593	TORRENT-MDL2875-00001304	TORRENT-MDL2875-00002091

[3] As explained in more detail below, because Torrent has produced all responsive documents that were "easily identifiable" and "relatively simple to retrieve," plaintiffs' demand that "Torrent identify the location of responsive documents[] to the extent that Torrent did not produce these documents" is moot.

Category	Beg Bates	End Bates
ANDA 091654	TORRENT-MDL2875-00002092	TORRENT-MDL2875-00002794
ANDA 202728	TORRENT-MDL2875-00002795	TORRENT-MDL2875-00004181
FDA Correspondence	TORRENT-MDL2875-00004182 TORRENT-MDL2875-00004219	TORRENT-MDL2875-00004217 TORRENT-MDL2875-00004253
Customer List	TORRENT-MDL2875-00004218	TORRENT-MDL2875-00004218

Category	Beg Bates	End Bates
FDA Correspondence	TORRENT-MDL2875-00004303	TORRENT-MDL2875-00004343

2. **Torrent has complied with ¶ 6(b)(3)(1) and (2) of the Core Discovery Order.**[4] These subsections of ¶ 6 require that responding defendants produce "[c]ommunications with the FDA relating to or concerning: (1) the ARB Recalls, [and] (2) the investigation into the cause of the alleged contamination…" In compliance with these subsections, Torrent has produced 83 documents evidencing communications with the FDA. Torrent did not limit its production in any way. Rather, Torrent has produced all documents responsive to this request that were "easily identifiable" and "relatively simple to retrieve," per the Court's directive in the Core Discovery Order.

   Additionally, contrary to plaintiffs' suggestion, ¶ 6(b)(3)(2) does not require Torrent to produce any "product testing results." Rather, all that is required are communications with the FDA regarding "the investigation into the cause of the alleged contamination." Thus, plaintiffs' demand that Torrent produce "all testing results" fails.

3. **Torrent has complied with ¶ 6(b)(3)(6).** This subsection of ¶ 6 requires that responding defendants produce "[c]ommunications with the FDA relating to or concerning…a list of all United States customers from 2010 to present." Torrent produced a customer list responsive to this request, and is confirming whether that list is inclusive of all Torrent's United States customers from 2010 to present. If it is not, Torrent will supplement its production.

[4] As explained above, *supra* at pp. 3-4, Torrent has not produced "Form 483's, Establishment Inspection Reports, CGMP inspection reports, and warning letters, [or]…responses to same" because Torrent is a finished dose manufacturer; Torrent is not a "facility that ***manufactured or supplied the API at issue***." Core Discovery Order at ¶ 6(a)(3).

D. The Teva Defendants

The Teva Defendants respond as follows to the individual issues raised by plaintiffs. Counsel for the Teva Defendants have met and conferred with plaintiffs' counsel on these issues, and will continue to work to resolve disputes ahead of the in-person conference.

1. **Documents regarding the custodial file of Constance Truemper, Teva's Regulatory Compliance Manager.** The documents plaintiffs claim were wrongfully withheld are not responsive to the Core Discovery Order as they are strictly internal communications with other Teva employees. The Core Discovery Order requires production of "[c]ommunications with the FDA relating to or concerning: (1) the ARB recalls…" Dkt. 88 at ¶ 6(a)(3); ¶ 6(b)(2). That is exactly what Teva produced. Communications between and among Teva employees are not required to be produced at this time. The identified communications from Constance Truemper are primarily forwarding emails, many without any text in the body of said email, intended to ensure communications with the FDA were shared internally. Teva collected these non-responsive emails in order to collect and produce the attached communications with the FDA, which are responsive to the Core Discovery Order.

2. **Failure to comply with ¶ 6(b)(1) of the Core Discovery Order (ANDA file production).** Plaintiffs are incorrect that Teva did not produce documents for ANDA 090642 and ANDA 077530. Teva's production contains the documents for both of these ANDAs in the format which they are maintained by the responding entities. To the extent additional ANDA materials are identified, Teva will supplement its production as soon as practicable.

3. **Failure to comply with ¶ 6(b)(2) of the Core Discovery (testing results).** The Core Discovery Order requires production of "[c]ommunications with the FDA relating to or concerning…(3) efforts to contain, remove or detect the contamination…" Id. at ¶ 6(a)(3); ¶ 6(b)(2). The FDA requested that Teva provide testing of its US valsartan products, and Teva is in the process of responding to FDA's requests regarding the testing of samples from each of its valsartan ANDAs and will supplement its core discovery production as soon as it finalizes and submits its responses to FDA.

4. **Failure to comply with ¶ 6(b)(3)(5) of the Core Discovery (facility inspection reports, documents and correspondence).** The Core Discovery Order requires Defendants to produce "all FDA Form 483's, Establishment Inspection Reports, CGMP inspection reports, and warning letters, as well as the responding defendants' responses to same, regarding any facility that manufactured or supplied the API at issue." Id. at ¶ 6(b)(3). Accordingly, Defendants are not required to produce the aforementioned documents for facilities that did not manufacture or supply valsartan API. The Court did not order production of these documents for finished dose manufacturing facilities or any other facility which did not manufacture or supply the API at issue.

5. **Failure to comply with ¶ 6(b)(3)(6) of the Core Discovery (list of customers).** Teva produced a list of all 83 Actavis customers and 50 Teva customers that purchased valsartan products from January 1, 2012 through the date of the recalls. Plaintiffs' claim that Teva's customer list only identified customers with non-expired product is incorrect.

E. Mylan Pharmaceuticals Inc.

In their letter dated July 31, plaintiffs identified five purported deficiencies in Mylan's core discovery production. Mylan responded to those concerns by letter dated August 7. During a follow-up meet-and-confer teleconference on August 12, Mylan and plaintiffs were able to clarify or resolve several disputes. At this juncture, there remain three outstanding Mylan-specific issues:

1. Whether Mylan must produce ANDA 204743, which concerns a product that has never been sold in United States;

2. Whether Mylan must produce documents reflecting FDA's inspection of finished dose manufacturing facilities even though the Core Discovery Order expressly limits such discovery to the facilities "that manufactured or supplied the API at issue," Dkt. 88 at ¶ 6(a)(3)(5); and

3. Whether, in addition to the already produced lists of API customers and entities that received its recalled finished dose product, Mylan also must provide a list of all finished dose customers in United States going back to 2012.

The parties will be prepared to present and elaborate upon their respective positions at the August 14 Status Conference.

F. Hetero USA, Inc.

By letter dated July 31, plaintiffs identified several purported deficiencies with Hetero USA, Inc.'s ("Hetero USA") production. On August 5, Hetero USA responded by letter emailed to plaintiffs addressing the issues raised. As to certain technical ESI aspects of the production, Hetero USA has responded to plaintiffs on those issues and has received no response from plaintiffs indicating they have any remaining issues that the parties need to work together to address.

The other purported issues identified by plaintiffs relate to documents under ¶ 6(b)(3) of the Core Discovery Order. Hetero USA has searched for additional readily identifiable and relatively simple to retrieve documents beyond those it has already produced and is preparing a supplemental production of FDA communications. These communications include, for example, information about the API manufacturer, investigation into the alleged contamination, testing results related to the medication at issue, and customer information. Hetero USA hopes to make this production prior to the upcoming conference. Once completed, Hetero USA will have

produced the core discovery within its possession, custody, and control pursuant to the Core Discovery Order. For other items at issue, Hetero USA has also referred plaintiffs to either co-defendant Hetero Labs Ltd. (such as FDA Form 483's, Establishment Inspection Reports, and CGMP inspection reports) or co-defendant Camber Pharmaceuticals Inc. (customer lists).

Plaintiffs' July 31 letter also inquires as to what steps, if any, Hetero USA has undertaken to obtain responsive documents from other entities. Respectfully, this request is outside the scope of the Core Discovery Order, which required Hetero USA to identify where core discovery is located "[t]o the extent [they] contend[] [they] do not have possession, custody or control of any of the listed documents." Hetero USA has done so, as noted above, and has further identified the address for Hetero Labs Ltd. in India where further documents responsive to the Core Discovery Order are located. Hetero USA does not know if Hetero Labs Ltd. has been served; but no proof of service has been filed with the Court to-date.[5]

Respectfully submitted,

/s/ Seth A. Goldberg

Seth A. Goldberg

SAG
Enclosures

cc: Adam Slater, Esq. (*via email*, *for distribution to Plaintiffs' Counsel*)
Jessica Priselac, Esq. (*via email*, *for distribution to Defendants' Counsel*)
Lori G. Cohen, Esq. (*via email*)
Clem C. Trischler, Esq. (*via email*)

[5] Hetero USA would like to point out that it was served with the first of these lawsuits in October 2018. Had plaintiffs initiated service through the Hague on Hetero Labs Ltd. at that time, service would likely have already been completed and Hetero Labs Ltd., as the actual API manufacturer and finished dose manufacturer, would have been responsible for producing core discovery in this litigation rather than Hetero USA. Hetero USA has incurred more than nominal costs in complying with the Core Discovery Order; this could have been avoided altogether had plaintiffs more timely acted to initiate service on Hetero Labs.